

Federal Register

Thursday
February 19, 1981

Part III

The President

Executive Order 12291—
Federal Regulation

Presidential Documents

Title 3—

The President

Executive Order 12291 of February 17, 1981

Federal Regulation

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations, it is hereby ordered as follows:

Section 1. *Definitions.* For the purposes of this Order:

(a) "Regulation" or "rule" means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency, but does not include:

(1) Administrative actions governed by the provisions of Sections 558 and 557 of Title 5 of the United States Code;

(2) Regulations issued with respect to a military or foreign affairs function of the United States; or

(3) Regulations related to agency organization, management, or personnel.

(b) "Major rule" means any regulation that is likely to result in:

(1) An annual effect on the economy of \$100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

(c) "Director" means the Director of the Office of Management and Budget.

(d) "Agency" means any authority of the United States that is an "agency" under 41 U.S.C. 3502(1), excluding those agencies specified in 44 U.S.C. 3502(10).

(e) "Task Force" means the Presidential Task Force on Regulatory Relief.

Sec. 2. *General Requirements.* In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by law, shall adhere to the following requirements:

(a) Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;

(b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society;

(c) Regulatory objectives shall be chosen to maximize the net benefits to society;

(d) Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and

(e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the

particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Sec. 3. Regulatory Impact Analysis and Review.

(a) In order to implement Section 2 of this Order, each agency shall, in connection with every major rule, prepare, and to the extent permitted by law consider, a Regulatory Impact Analysis. Such Analyses may be combined with any Regulatory Flexibility Analyses performed under 5 U.S.C. 603 and 604.

(b) Each agency shall initially determine whether a rule it intends to propose or to issue is a major rule, *provided that*, the Director, subject to the direction of the Task Force, shall have authority, in accordance with Sections 1(b) and 2 of this Order, to prescribe criteria for making such determinations, to order a rule to be treated as a major rule, and to require any set of related rules to be considered together as a major rule.

(c) Except as provided in Section 8 of this Order, agencies shall prepare Regulatory Impact Analyses of major rules and transmit them, along with all notices of proposed rulemaking and all final rules, to the Director as follows:

(1) If no notice of proposed rulemaking is to be published for a proposed major rule that is not an emergency rule, the agency shall prepare only a final Regulatory Impact Analysis, which shall be transmitted, along with the proposed rule, to the Director at least 60 days prior to the publication of the major rule as a final rule;

(2) With respect to all other major rules, the agency shall prepare a preliminary Regulatory Impact Analysis, which shall be transmitted, along with a notice of proposed rulemaking, to the Director at least 60 days prior to the publication of a notice of proposed rulemaking, and a final Regulatory Impact Analysis, which shall be transmitted along with the final rule at least 30 days prior to the publication of the major rule as a final rule;

(3) For all rules other than major rules, agencies shall submit to the Director, at least 10 days prior to publication, every notice of proposed rulemaking and final rule.

(d) To permit each proposed major rule to be analyzed in light of the requirements stated in Section 2 of this Order, each preliminary and final Regulatory Impact Analysis shall contain the following information:

(1) A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits;

(2) A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs;

(3) A determination of the potential net benefits of the rule, including an evaluation of effects that cannot be quantified in monetary terms;

(4) A description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of this potential benefit and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted; and

(5) Unless covered by the description required under paragraph (4) of this subsection, an explanation of any legal reasons why the rule cannot be based on the requirements set forth in Section 2 of this Order.

(e) (1) The Director, subject to the direction of the Task Force, which shall resolve any issues raised under this Order or ensure that they are presented to the President, is authorized to review any preliminary or final Regulatory Impact Analysis, notice of proposed rulemaking, or final rule based on the requirements of this Order.

(2) The Director shall be deemed to have concluded review unless the Director advises an agency to the contrary under subsection (f) of this Section:

schedule for completing action on any major rule for which the agency has issued a notice of proposed rulemaking;

(2) The name and telephone number of a knowledgeable agency official for each item on the agenda; and

(3) A list of existing regulations to be reviewed under the terms of this Order, and a brief discussion of each such regulation.

(b) The Director, subject to the direction of the Task Force, may, to the extent permitted by law:

(1) Require agencies to provide additional information in an agenda; and

(2) Require publication of the agenda in any form.

Sec. 6. *The Task Force and Office of Management and Budget.*

(a) To the extent permitted by law, the Director shall have authority, subject to the direction of the Task Force, to:

(1) Designate any proposed or existing rule as a major rule in accordance with Section 1(b) of this Order;

(2) Prepare and promulgate uniform standards for the identification of major rules and the development of Regulatory Impact Analyses;

(3) Require an agency to obtain and evaluate, in connection with a regulation, any additional relevant data from any appropriate source;

(4) Waive the requirements of Sections 3, 4, or 7 of this Order with respect to any proposed or existing major rule;

(5) Identify duplicative, overlapping and conflicting rules, existing or proposed, and existing or proposed rules that are inconsistent with the policies underlying statutes governing agencies other than the issuing agency or with the purposes of this Order, and, in each such case, require appropriate interagency consultation to minimize or eliminate such duplication, overlap, or conflict;

(6) Develop procedures for estimating the annual benefits and costs of agency regulations, on both an aggregate and economic or industrial sector basis, for purposes of compiling a regulatory budget;

(7) In consultation with interested agencies, prepare for consideration by the President recommendations for changes in the agencies' statutes; and

(8) Monitor agency compliance with the requirements of this Order and advise the President with respect to such compliance.

(b) The Director, subject to the direction of the Task Force, is authorized to establish procedures for the performance of all functions vested in the Director by this Order. The Director shall take appropriate steps to coordinate the implementation of the analysis, transmittal, review, and clearance provisions of this Order with the authorities and requirements provided for or imposed upon the Director and agencies under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, and the Paperwork Reduction Plan Act of 1980, 44 U.S.C. 3501 *et seq.*

Sec. 7. *Pending Regulations.*

(a) To the extent necessary to permit reconsideration in accordance with this Order, agencies shall, except as provided in Section 8 of this Order, suspend or postpone the effective dates of all major rules that they have promulgated in final form as of the date of this Order, but that have not yet become effective, excluding:

(1) Major rules that cannot legally be postponed or suspended;

(2) Major rules that, for good cause, ought to become effective as final rules without reconsideration. Agencies shall prepare, in accordance with Section 3 of this Order, a final Regulatory Impact Analysis for each major rule that they suspend or postpone.

(i) This Section does not supersede the President's Memorandum of January 29, 1981, entitled "Postponement of Pending Regulations", which shall remain in effect until March 30, 1981.

(j) In complying with this Section, agencies shall comply with all applicable provisions of the Administrative Procedure Act, and with any other procedural requirements made applicable to the agencies by other statutes.

Sec. 8. Exemptions.

(a) The procedures prescribed by this Order shall not apply to:

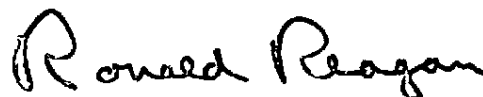
(1) Any regulation that responds to an emergency situation, *provided that*, any such regulation shall be reported to the Director as soon as is practicable, the agency shall publish in the Federal Register a statement of the reasons why it is impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency shall prepare and transmit as soon as is practicable a Regulatory Impact Analysis of any such major rule; and

(2) Any regulation for which consideration or reconsideration under the terms of this Order would conflict with deadlines imposed by statute or by judicial order, *provided that*, any such regulation shall be reported to the Director together with a brief explanation of the conflict, the agency shall publish in the Federal Register a statement of the reasons why it is impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency, in consultation with the Director, shall adhere to the requirements of this Order to the extent permitted by statutory or judicial deadlines.

(b) The Director, subject to the direction of the Task Force, may, in accordance with the purposes of this Order, exempt any class or category of regulations from any or all requirements of this Order.

Sec. 9. Judicial Review. This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. The determinations made by agencies under Section 4 of this Order, and any Regulatory Impact Analyses for any rule, shall be made part of the whole record of agency action in connection with the rule.

Sec. 10. Revocations. Executive Orders No. 12044, as amended, and No. 12174 are revoked.



THE WHITE HOUSE,
February 17, 1981.

Introduction

In recent years, Americans have become more and more concerned about cancer and the environment. A steady flow of disturbing news articles, magazine features and television specials reflected the concern, and in turn raise more questions than they answer.

For example, headlines declare a dramatic rise in the national cancer deathrate. It seems that almost on a weekly basis, one governmental agency or another announces another substance has been found to cause cancer. Television newscasters and magazine writers often refer to an "epidemic" of cancer.

As people become more and more concerned about cancer, and the presence of cancer-causing agents in our air, water, food and workplaces, they begin to ask some disturbing questions:

- Is cancer out of control?
- Is it killing more and more people every year?
- Will things continue to get worse as we use more and more chemicals?
- Are chemicals the major cause of cancer?
- Is our country paying too high a price for its sophisticated technological way of life?

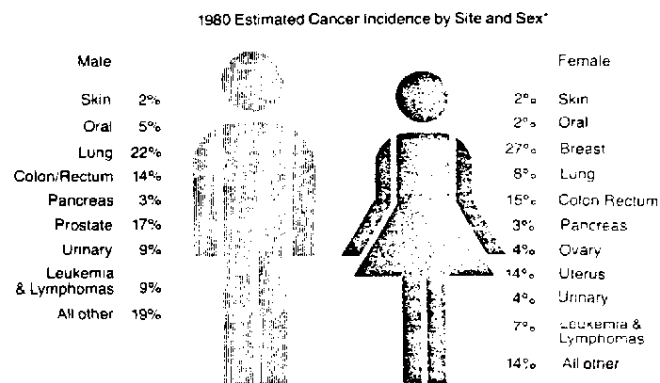
Scientists don't know all the answers about cancer, yet. But a great deal has been learned in recent years. We know that:

- Cancer is not out of control or epidemic. In fact, cancer is not even on the increase, according to the National Cancer Institute.
- More and more people are being cured. About half of all new cases of cancer could be cured with early diagnosis and treatment.
- Lifestyle factors, such as smoking, drinking and diet are related to, if not the direct cause of as many as 75 percent of cancer cases.

The facts

The American Cancer Society estimates that 785,000 new cases of cancer will be diagnosed each year. If current rates prevail, one in four Americans now living will eventually develop some form of cancer, although many will die of other causes.

Some types of cancer occur more frequently than others. Among men, lung cancer is now the most common form, followed by prostate and colon-rectum cancers. Among women, breast cancer is the leader followed by colon-rectum and uterine cancers. The chart below shows estimates of the proportion of all cancers that occur at each major body site.

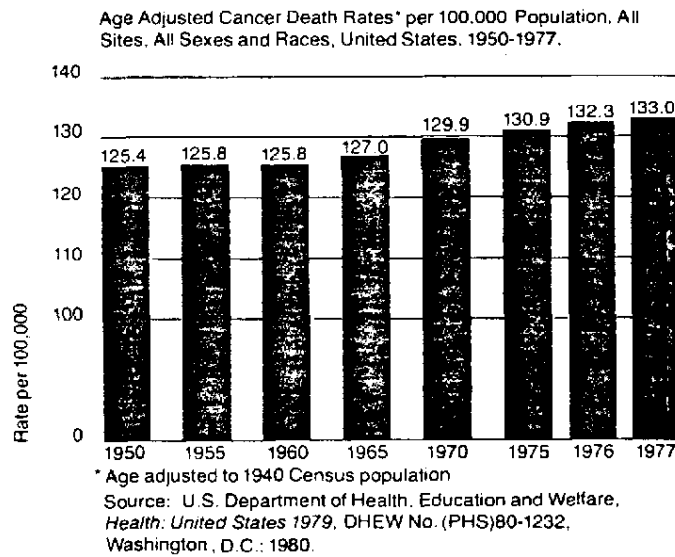


* Excluding non-melanoma skin cancer and carcinoma in situ
Source: American Cancer Society, 1980 *Cancer Facts and Figures*.
New York: 1979.

Cancer is the second leading cause of death in the United States after diseases of the heart and circulatory system.

The American Cancer Society estimates that about 405,000 Americans will die of cancer in 1980. Of these, 101,000, or 25 percent, will die of lung

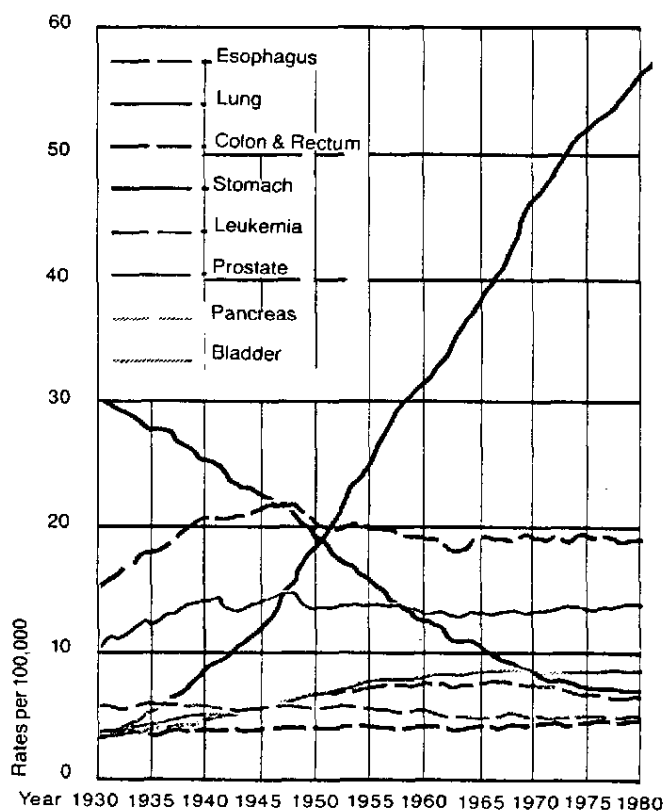
cancer. There has been a gradual rise in the combined age adjusted cancer death rate since, 1950, as shown below.



In general, the cancer death rate has increased among men and decreased among women. Yet except for the large increases in lung cancer deaths, age adjusted death rates for other types of cancer are leveling off, and in some cases declining.

As is evident in the charts below, the only cancer deaths that qualify as "epidemic" are those from lung cancer. The rapid increase in lung cancer deaths is most evident for men, but has also occurred in recent years for women as well. This delayed increase in female lung cancer death rates is consistent with the rise in female cigarette smoking that followed World War II. In contrast, men began smoking in large numbers after World War I, almost 30 years earlier. The usual latency period for lung cancer is 20 to 30 years which accounts for the delayed increase in the female rates.

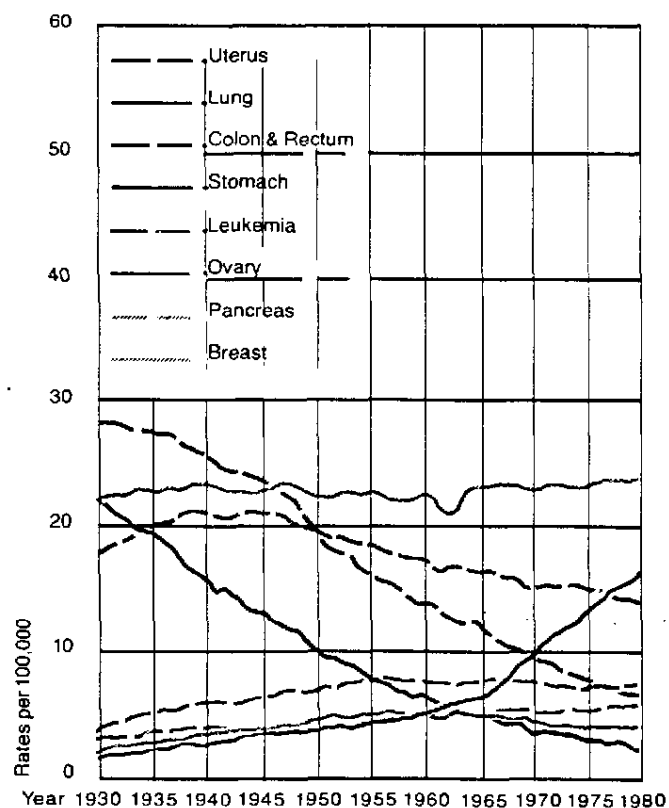
Age Adjusted Male Cancer Death Rates* per 100,000
Population, Selected Body Sites, United States, 1930-1980



*Standardized on The Age Distribution of The 1940
U.S. Census Population

Source: Silverberg, E., Cancer Statistics, 1980,
CA-A Cancer Journal for Clinicians,
30(1): 23, 1980.

Age Adjusted Female Cancer Death Rates* per 100,000
Population, Selected Body Sites, United States, 1930-1980



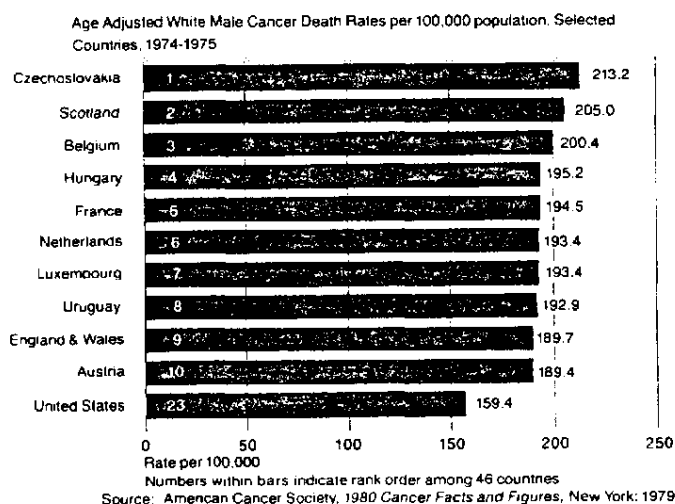
*Standardized on The Age Distribution of The 1940
U.S. Census Population

Source: Silverberg, E., Cancer Statistics, 1980,
CA-A Cancer Journal for Clinicians,
30(1): 23, 1980.

An international comparison

It is widely believed that the United States has a high cancer death rate compared with other countries. One network television program on cancer opened with the statement: "The news tonight is that the United States is number one in cancer. The National Cancer Institute estimates that if you're living in America your chances of getting cancer are higher than anywhere else in the world."

However, information collected by the World Health Organization and analyzed by the American Cancer Society gives a much different view. In a comparison of cancer death rates in 46 countries, the U.S. ranked 23rd for male and 19th for female cancer deaths. Czechoslovakia holds the dubious honor of being "number one" followed by Scotland, Belgium, Hungary and France. (See chart below). According to this survey, the U.S. white male death rate, was 159 per 100,000.



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What causes human cancer?

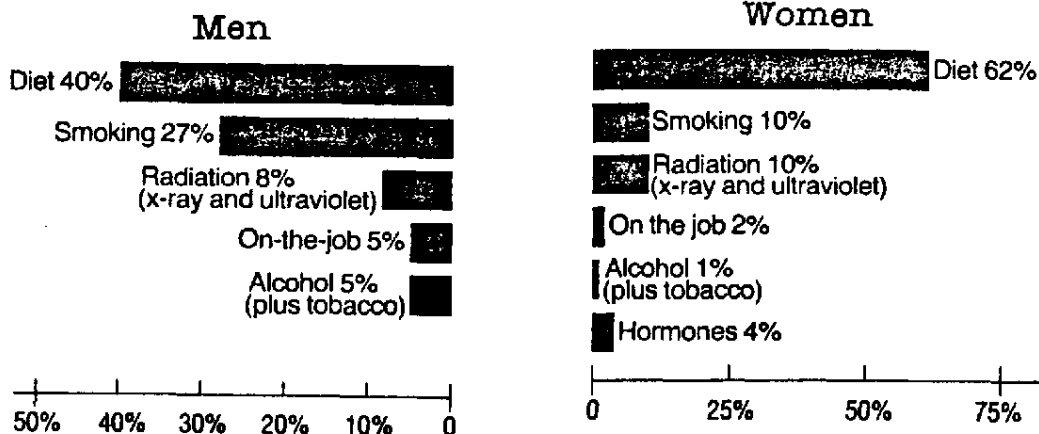
Since 1970, professional and popular articles have frequently cited an estimate that "80 to 90 percent of all cancers are environmentally induced." This estimate was originally calculated by the International Agency for Research on Cancer (IARC), a World Health Organization affiliate. It has often been misinterpreted, leaving the mistaken impression that 80 to 90 percent of all cancers are due to known environmental factors such as air and water pollution, industrial chemicals or food chemicals and contaminants.

However, the "environment" is not limited solely to physical surroundings and manmade chemicals. Many scientists now believe that cultural and personal habits contribute more to causing cancer than environmental pollution or toxic chemicals. (See chart below). In its broadest sense, the environment encompasses such factors as smoking, diet, sexual and reproductive patterns, alcohol consumption, sunbathing, and other aspects of lifestyle, as well as purely physical surroundings.

Causes of cancer

Percent of 1976 cancer cases which could be directly connected to a cause in the patient's environment.

Source of graph data:
Wynder, Gori study reported by
National Cancer Institute



When analyzing the question "what causes cancer?", it makes more sense to talk about the concept of risk rather than cause. Cancer is the result of a complex interaction among a number of different factors. It is difficult or impossible to identify a specific cause for any cancer. So it makes sense to focus on those factors which increase a person's risk of getting cancer. By eliminating or reducing exposure to these cancer risk factors, we can successfully prevent some cancers despite our limited knowledge of the basic causes of cancer.

Tobacco

National incidence and mortality figures confirm the drastic unprecedented rise in lung cancer in the United States. Yet before 1930, lung cancer was a rare disease. In 1912, a physician commenting on U.S. disease patterns wrote: "There is nearly a complete consensus of opinion that (cancer) of the lung (is) among the rarest forms of disease." However, by 1950, clinical and statistical evidence clearly demonstrated a significant increase in lung cancer among men.

Since 1970, this same pattern of increasing incidence has also been observed among American women. Numerous clinical, epidemiological and laboratory studies have confirmed that the increase in lung cancer is directly related to cigarette smoking. It has been shown that lung cancer death rates are eight to 15 times higher among male cigarette smokers than among male nonsmokers. Although precise estimates of the number of lung cancer deaths caused by smoking vary, most experts agree that at least 80 percent of all lung cancer deaths are the result of cigarette smoking.

Diet

The impact of dietary habits in causing cancer is not fully understood. But the evidence accumulated to date deserves attention.

There are three ways diet may affect cancer risk. First, dietary deficiencies may fail to provide some natural form of protection. Recent theories about the role of fiber in the diet are an example of this type of cancer risk. Some research suggests that diets which contain little or no fiber may, in combination with a high fat/high calories intake increase the risk of colon cancer.

Second, a food may contain some cancer-causing agent either as a natural part of its make-up, a deliberate additive or as an accidental contaminant.

Third, the way diet may affect cancer risks is through excessive consumption. Some preliminary evidence has suggested that diets rich in fats and calories may increase the risks of cancers of the breast, prostate, colon and uterus.

Also cultural differences that determine the way foods are prepared and preserved may provide a clue to the cause of stomach cancer. In Japan, where a large proportion of the diet consists of salted fish and vegetables, the incidence of stomach cancer is among the highest in the world. In the United States, in contrast, where refrigeration and antioxidants have replaced salt and spices as preservatives, the stomach cancer incidence is the lowest in the world. More research is needed to confirm this.

Alcohol

Although evidence of alcohol's direct cancer-causing effects on either humans or animals has been generally negative, its action in combination with other cancer-causing agents has been documented. Heavy alcohol consumption in combination with heavy cigarette smoking increases the risks for cancers of the mouth and throat.

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Radiation

Exposure to ionizing radiation, through medical x-rays, for example, increases the risk of developing leukemia and skin cancer. As early as 1944,

researchers noted that radiologists were more likely than other physicians to develop leukemia. Recent attention to this cancer risk has resulted in recommendations against the use of x-rays as a routine medical practice. However, experts agree that when x-rays are used prudently, their diagnostic and therapeutic benefits far outweigh their small cancer risk.

Sunlight

The most widespread environmental cause of cancer, accounting for the majority of superficial skin cancers, is solar radiation. Skin cancer, however, is rarely fatal and is not included in most statistical estimates of U.S. cancer patterns. Fortunately, most of the sun's harmful ultraviolet radiation is filtered out by the atmospheric ozone layer before it reaches the earth.

Occupation

High dose, long-term exposure to a number of industrial chemicals and manufacturing processes, including asbestos, vinyl chloride, nickel refining, and dye manufacturing can increase risk of several types of cancer. To date, approximately 20 industrial chemicals have been confirmed as potential causes of cancer in humans. An additional 200-300 are suspected potential causes on the basis of animal test evidence. As with other cancer risks, occupational risks depend on the length and degree of exposure, the potency of the chemical agent, possible interactions with other chemicals, and lifestyle factors such as cigarette and alcohol consumption.

Cancer and the environment: an overview

Despite the popular conception that the United States is suffering from an "epidemic" of cancer, the scientific evidence collected to date does not support this view. With the exception of lung cancer, age adjusted cancer death rates for most other forms of cancer have decreased or remained constant for the past 50 years.

VVC 000009606

The exact number of cancers that can be eliminated by sound preventive methods is unknown, but the percentage is undoubtedly substantial. Eliminating the effects of cigarette smoking alone would eventually reduce cancer cases and deaths between 15 and 35 percent. If the relationship between dietary factors and intestinal cancer is confirmed, a similar reduction might be expected from changes in eating habits. Some small number of potential cancer cases will likely be prevented as a result of recent laws to regulate occupational exposures to toxic chemicals.

The probability of finding an effective cure for cancer soon is remote, but preventive measures can successfully reduce the risk of cancer. To this end, current scientific knowledge suggests that prevention efforts should be focused on personal activities, especially smoking, sunbathing and alcohol consumption, rather than on food additives and pollution controls. It seems clear that successful efforts to reduce cancer may be more a matter of individual responsibility than government regulation.

CONOCO CHEMICALS
1981 Industrial Hygiene Seminar
La Mansion Del Rio Hotel
San Antonio, TX

PRELIMINARY AGENDA

WEDNESDAY, MARCH 4, 12:00 pm

Welcome/Administration

Employee Communication Program

- Channel 2 Videotape "Chemicals and Cancer"

M. Reynolds

J. Withey *M. Reynolds*

Medical Testing Program

- Past and Present: Policies and Procedures
- Purpose: Management's View

T. Grumbles

J. Hall

Dr. Massad

R. Lehmkuhl

Regulatory Update ←

THURSDAY, MARCH 5, 8:00-5:00 pm

Industrial Hygiene Policy and Procedures

- Exposure Abatement Program
- Deregulation of Areas
- Written Determinations
- Computerized Data Storage System Update
- Radiation
- New Material Safety Data Sheets

T. Grumbles

Legal Presentation and Discussion

- Contractor Policies & Responsibilities
- OSHA Inspection Guide

Legal Dept.

Air Sampling Methods

- Passive Dosimetry
- Asbestos Identification and Sampling

P. Fetzer

FRIDAY, MARCH 6, 8:00-12:00pm

Chemicals Mortality Study Update; NCI Baltimore Study

Industrial Hygiene Audit Program ←

Roundtable Discussion - EO and Benzene

VVC 000009608